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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,525

02/27/2004

Richard James Cawthray

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07/03/2008

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,525	Applicant(s) CAWTHRAY ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,11,14,15,21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,11,14,15 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in Response to the Amendment filed April 16, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness – (Previous Rejection)

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strein (US 5,366,965). The rejection is maintained in regards to claims 1, 2, 4, 5, 11, 14, 15 and 21. Claims 3, 6-10, 12, 13 and 16-20 are cancelled.

Applicant's Arguments

Applicant argues Strein differs from the instant claims based on the cyclical nature of bisphosphonate dosing relative to the continuous dosing recited in Claim 1. The bisphosphonate is dosed on only one day of the intermittent period and the rest period lasts for 20 - 120 days. It is only during the rest period that Strein suggests use of a nutrient such as calcium or vitamin D. A placebo is taken during the remaining days of the inhibiting period. Thus, Strein discloses a cyclical regimen in which a bisphosphonate is dosed on at least two days during an inhibiting period, wherein those two days are separated by dosing with or without a nutrient during the remaining days of the inhibiting period; after that is the rest period in which no bisphosphonate is dosed. As such there are long periods within the inhibiting period that no bisphosphonate is

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dosed, followed by another long period over the entire rest period (20 - 120 days) in which no bisphosphonate is dosed. In contrast to Strein, the claims of the present invention are directed to kits in which bisphosphonate is dosed in accordance with a continuous, not cyclical, regimen. See section (a) of Claim 1 which directs administration of bisphosphonate continuously. Moreover, Applicants have amended the claims herein to recite a more specific regimen in which the kit is arranged for once-weekly dosing of the bisphosphonate by providing 4 unit doses of the bisphosphonate and 24 unit doses of the nutrient. These arguments are not persuasive.

Examiner's Response

Strein discloses a regimen for treatment of osteoporosis comprising administering to a patient a drug for only one day of an intermittent period wherein there are at least two periods lasting 2 to 14 days (col. 3, line 62 to col. 4, line 20). The recitation of at least two includes 4 periods lasting 7 days, which would encompass one dosage unit per week (see col. 4, lines 7-9). The resting period may last 20-120 days which encompass 24 days, therefore meeting the limitation of the claims reciting 24 unit doses of a nutrient. The reference also discloses "For example, in a treatment regime comprising cycles each including inhibiting periods which consist of 3 intermittent periods, each seven days long, it would be suitable to group dosages in sets of three, one for each of the three intermittent periods during each inhibiting period, and to indicate beside each dosage the date on which that dosage should be administered. Alternatively or additionally, it would be suitable to include a number of placebo dosages

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(preferably in a form similar to the polyphosphonate dosages and comprising an inert material or, e.g., a nutrient supplement) equal to the number of days for which polyphosphonate is not administered” (col. 6, lines 25-44). This also encompasses the instant claims by suggesting a nutrient be administered the six days in which the phosphonates is not during the inhibiting period. In regards to the cylindrical packaging disclosed in the reference, a claimed device is not patentably distinct from the prior art if the claimed device would not perform differently than the prior art device. Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), previously cited in the prior office action. The blister pack of the reference serves to provide a memory aid on the card, e.g., in the form of numbers adjacent to the dosages, which numbers correspond to the days in the regimen in which the dosages should be administered, e.g., the date (col. 6, lines 55-62), which is the same purpose of the blister pack as recited in claim 2. Although Applicant recites a “continuous” regimen, it does not define what is period of time encompasses “continuous”. The only guidance in the instant disclosure is the recitation of “once a week for an unspecified period of time”, which is encompassed by the reference. Furthermore the claims are drawn to a kit and not an actual method of administering the components of a kit. Therefore the reference encompasses the instant claims.

Claims 1, 2, 4, 5, 11, 14, 15 and 21 are rejected.

Claim 24 is withdrawn.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612